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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/890,266	03/27/2002	Tadao Ohno	P21324	9535

7055 7590 03/29/2005

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EXAMINER

YU, MISOOK

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 03/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/890,266

Applicant(s)

OHNO ET AL.

Examiner

MISOOK YU, Ph.D.

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 March 2002 and 08 August 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 02/04/2002, 07/30/2002, 02/27/2004
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

12/10/2001

DETAILED ACTION

Claims 1-16 are pending and examined on merits.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 6, and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 98/16238 (23 April 1998, IDS filed on 30 July 2002).

The base claims 1, 2, and 6 are interpreted as drawn to a composition comprising two main components of (1) “a microparticle” or “lysate” from one of the three Markush groups of a tumor tissue, a tumor cell, and a component thereof, and (2) at least one cytokine or cytokine-inducing agent, wherein the dependent claims 3, and 7 further specify that the composition of the base claims further comprises an adjuvant. After consulting the specification at page 7, second paragraph, where it discloses “The fixation method to prepare the solidified tumor material is not particularly limited, and any means available to those skilled in the art may be applied. For example, when a tissue fixing agent is used, neutral formalin, glutaraldehyde, an alcohol such as methanol and ethanol and the like can be used”, the limitation “solidified tumor material” in claims 1 and 3, is interpreted as fixed tumor cells. As for the limitation “lysate” in claims 2, and 3, the Office consults the specification at page 8, where “lysate” is defined as “a state of dispersion...in an aqueous medium such as water, physiological saline”.

WO 98/16238 teaches "the vaccine of this invention comprises two components. The first is a source of tumor antigen...A convenient source of tumor-associated antigen is tumor cells...The second component is a stimulated lymphocyte population that can participate in stimulation of the patient's immune system to produce an anti-tumor response. In particular, the stimulated lymphocyte population comprises lymphocytes that are allogeneic to the patient" (note page 6 lines 21-30), "The inactivated tumor cell may be substituted by an alternative source of tumor-associated antigen, such as a tumor cell homogenate, detergent lysate, or a purified derivative thereof" (note page 6, line 38-40), "Cancer cells for use as a tumor antigen source can alternatively be fixed with such agents as glutaraldehyde, paraformaldehyde, or formalin. They may also be solubilized in an ionic or non-ionic detergent, such as deoxycholate or octyl glucoside, or lysed, for example using vaccinia virus" (note at page 15 lines 20-25). In summary, WO 98/16238 discloses the claimed invention has tumor tissue, tumor cell, or a component thereof to be in the form "lysate" or fixed with glutaraldehyde and other art-known agents. As for whether the second component meets the instantly claimed limitation "cytokine-inducing agent", the Office consulted Fig. 6 of WO 98/16238, where a cytokine (i.e. IFN-gamma or IL2) induction by the second component of a stimulated lymphocyte population. Thus, the second component of a stimulated lymphocyte population also meets the limitation of "cytokine-inducing agent" in instant claims 1, 2, and 6. As for the instantly claimed composition further comprising an adjuvant as claimed in instant claims 3, and 7, WO 98/16238 at page 23 lines 5-9 teaches "The vaccine comprises of this invention may optionally include additional active components

working independently or in concert with the tumor associated antigen and activated allogeneic cells. Such optional components include but not limited to isolated or recombinant cytokines, particularly those explicitly referred to in this disclosure, adjuvants, and other cell types.”

Thus, WO 98/16238 anticipates the instant claims 1-3, 6, and 7.

Claims 1, 2, 4-6, and 8-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Golumbek et al., (1993, IDS #5 filed on 12/10/2001, Cancer Res. Vol. 53, pages 5841-5844), or US Pat. 5, 861,159 (19 January 1999).

Based on the definition of microparticle as “a very small particle” in Merriam-Wester Online dictionary downloaded on 3/13/05 from the url..www.m-w.com, and the definition of lysate as “a state of dispersion...in an aqueous medium such as water, physiological saline” at the last paragraph of page 8 of the specification, claims 1, 2, 4-6, and 8-16 are broadly interpreted as drawn to a tumor vaccine comprising two main components of (1) at least one cytokine and (2) tumor material selected from the group consisting of a tumor tissue, a tumor cell, and a component thereof, wherein claims 4, 8, 9, and 13 specify that the cytokine of the base claims to be in an controlled-release form, and claims 5-12, and 14-16 specify the cytokine of the base claims to be GM-CSF.

Golumbek et al., at page 5841, right column, lines 7, and 8 teach “GM-CSF-containing microspheres to act as an adjuvant when mixed with irradiated tumor cells prior to immunization”.

US Pat. 5, 861,159 also teach a pharmaceutical composition comprising controlled release vehicle containing GM-CSF and a tumor antigen (note for example, claim 10).

Tumor cells of the prior art meet the limitation of “micro particles” or “lysate” because the tumor cells are very small particles or in state of dispersion in an aqueous solution. How the claimed “microparticle” or “lysate” is prepared is not given patentable weight because it is the same product produced by a different process meets the product limitation. In other words, if product of the prior art and the claimed product are same, then the prior art anticipates the claimed product regardless how the product is prepared.

Thus, either Golumbek et al., or US Pat. 5,861,159 anticipate instant claims 1, 2, 4-6, and 8-16.


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 571-272-0839. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MISOOK YU, Ph.D.
Examiner
Art Unit 1642


MISOOK YU
PATENT EXAMINER